

## 1. Product and company identification

### Product identifier

Trade name: 85H71=A - Maxosil

### Relevant identified uses of the substance or mixture and uses advised against

General use: HTV - Silicone for the production of prostheses with 85H71=B - Maxosil catalyst  
For orthopedic procedures.  
Reserved for industrial and professional use.

### Details of the supplier of the safety data sheet

Company name: Otto Bock Health Care  
Street/POB-No.: 3820 W. Great Lakes Drive  
Postal Code, city: Salt Lake City, UT 84120  
USA

WWW: [www.ottobockus.com](http://www.ottobockus.com)

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Department responsible for information:

Quality Department,  
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),  
Email: [USRegulatory@ottobock.com](mailto:USRegulatory@ottobock.com)

Additional information: Corporate headquarters:  
Ottobock SE & Co. KGaA  
Max-Näder-Straße 15  
Duderstadt  
Germany

### Emergency phone number

CHEMTREC, Telephone: +1 (800) 424-9300

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

## 2. Hazards identification

### Emergency overview

Appearance: Form: pasty  
Color: translucent, colorless  
Odor: weak  
Classification: This material is classified as not hazardous.

### Regulatory status

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200).

### Hazards not otherwise classified

Potentially explosive vapor/air mixtures may form.  
see section 11: Toxicological information

### 3. Composition / Information on ingredients

Chemical characterization: HTV - Silicone

Mixture on the basis of Polymethylhydrogensiloxane and Silicon dioxide

Additional information: The maximum workplace exposure limits are, where necessary, listed in section 8.

### 4. First aid measures

In case of inhalation: In case of heating: In case of inhalation of decomposition products, affected person should be moved into fresh air and kept still. Seek medical treatment in case of troubles.

Following skin contact: Remove mechanically with cloth or paper. Change contaminated clothing. Thoroughly wash skin with soap and water. Seek medical treatment in case of troubles.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.

In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Never give anything by mouth to an unconscious person. Rinse mouth with water. Do not induce vomiting. Seek medical treatment in case of troubles.

#### Most important symptoms/effects, acute and delayed

After eye contact: Mild irritant

#### Information to physician

Treat symptomatically.

### 5. Fire fighting measures

Flash point/flash point range:

> 392 °F (c.c.)

Auto-ignition temperature: Hydrogen: 752 °F

Suitable extinguishing media:

Water spray jet, Foam, dry chemical powder, carbon dioxide

Extinguishing media which must not be used for safety reasons:

Full water jet;

Dry chemical powder, alkaline

#### Specific hazards arising from the chemical

Combustible.

Potentially explosive vapor/air mixtures may form.

On heating or in case of fire toxic gases may form.

In case of fire may be liberated: highly inflammable gases (Danger of explosion!), hazardous dust, silicon dioxide, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information: Seal off endangered area. Cool endangered containers with water spray and, if possible, remove from danger zone. Use water spray jet to knock down vapors. Do not breathe fumes. Do not allow fire water to penetrate into surface or ground water.

## 6. Accidental release measures

Personal precautions:	Avoid contact with skin, eyes, and clothing. Wear suitable protective clothing. The use of protective glasses is generally recommended when handling chemicals.
Environmental precautions:	Do not empty into drains. (Danger of explosion!) Discharge into the environment must be avoided.
Methods for clean-up:	Take up mechanically, placing in appropriate containers for disposal. Final cleaning: Fouled surfaces must be immediately cleaned with suitable solvents. (solvents: refer to section 9, not: bases) Thoroughly clean surrounding area. Dispose of waste according to applicable legislation.
Additional information:	Remove all sources of ignition.

## 7. Handling and storage

### Handling

Advices on safe handling:	Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. When using do not eat, drink or smoke. Wash hands before breaks and after work.
Precautions against fire and explosion:	Keep away from sources of ignition. Potentially explosive vapor/air mixtures may form. Take standard precautions to prevent fire.
Specific use(s)	HTV - Silicone for the production of prostheses with 85H71=B - Maxosil catalyst for orthopedic procedures.

### Storage

Requirements for storerooms and containers:	Keep container tightly closed and in a well-ventilated place. Keep only in the original container. Do not drop, drag or bang the container. Store at room temperature.
Hints on joint storage:	Keep away from strong oxidizing agents, metal salts, metal-complexes, bases.

## 8. Exposure controls / personal protection

### Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
14808-60-7	Silicon dioxide (Quartz (SiO <sub>2</sub> ))	USA: ACGIH: TWA	0.025 mg/m <sup>3</sup> (respirable fraction)
		USA: IDLH: TWA	25 mg/m <sup>3</sup> (respirable fraction, cristobalite/tridymite)
		USA: IDLH: TWA	50 mg/m <sup>3</sup> (respirable fraction, quartz/tripoli)
		USA: NIOSH: TWA	0.05 mg/m <sup>3</sup> (respirable fraction)
		USA: OSHA: TWA	10 mg/m <sup>3</sup> /% SiO <sub>2</sub> + 2 (respirable fraction)
		USA: OSHA: TWA	250 mppcf/%SiO <sub>2</sub> +5 (fine dust)
		USA: OSHA: TWA	30 mg/m <sup>3</sup> /% SiO <sub>2</sub> + 2 (inhalable fraction)

Additional information: Silicon dioxide is embedded in the product and not available as respirable dusts.

### Engineering controls

Provide good ventilation and/or an exhaust system in the work area.  
See also information in chapter 7, section storage.

### Personal protection equipment (PPE)

Eye/face protection: Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010

Skin protection: Suitable protective clothing.  
Protective gloves according to OSHA Standard - 29 CFR: 1910.138  
Glove material: Polyethylene/polypropylene  
Breakthrough time: > 480 min.  
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Respiratory protection is not necessary if room is well ventilated.

General hygiene considerations:  
Avoid contact with skin, eyes, and clothing. Change contaminated clothing. Wash hands before breaks and after work.  
Have eye wash bottle or eye rinse ready at work place. When using do not eat or drink.

### Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Appearance:	Form: pasty Color: translucent, colorless
Odor:	weak
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	> 392 °F (c.c.)
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	LEL (Lower Explosion Limit): Hydrogen: 4.00 Vol-% UEL (Upper Explosive Limit): Hydrogen: 74.00 Vol-%
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 77 °F: approx. 1.12 g/cm <sup>3</sup>
Solubility:	slightly soluble in acetone, alcohol (ethanol) partially soluble/dispersible in aliphatic hydrocarbons, aromatic hydrocarbons (toluene, xylene), chlorinated hydrocarbons
Water solubility:	practically insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	Hydrogen: 752 °F
Thermal decomposition:	> 200 °C

Viscosity, dynamic: at 77 °F: approx. 25,000 mPa\*s

## 10. Stability and reactivity

Reactivity:	No data available
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	Potentially explosive vapor/air mixtures may form.
Conditions to avoid:	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge.
Incompatible materials:	Reacts with strong oxidizing agents. Formation of hydrogen (max. 3 l/kg) with metal salts, metal-complexes and bases. (Danger of explosion!)
Hazardous decomposition products:	On heating or in case of fire toxic gases may form. In case of fire may be liberated: highly inflammable gases (Danger of explosion!), hazardous dust, silicon dioxide, carbon monoxide and carbon dioxide. decomposition products: hydrogen (max. 3 l/kg)
Thermal decomposition:	> 200 °C

## 11. Toxicological information

### Toxicological tests

Acute toxicity:	LD50 Rat, oral: > 2,000 mg/kg LD50 Rat, percutan: > 2,000 mg/kg
Toxicological effects:	Acute toxicity (oral): Based on available data, the classification criteria are not met. Acute toxicity (dermal): Based on available data, the classification criteria are not met. Acute toxicity (inhalative): Lack of data. Skin corrosion/irritation: Lack of data. Serious eye damage/irritation: Lack of data. Sensitisation to the respiratory tract: Lack of data. Skin sensitisation: Based on available data, the classification criteria are not met. Not known to cause sensitization. Germ cell mutagenicity/Genotoxicity: Lack of data. Carcinogenicity: Lack of data. Reproductive toxicity: Lack of data. Effects on or via lactation: Lack of data. Specific target organ toxicity (single exposure): Lack of data. Specific target organ toxicity (repeated exposure): Lack of data. Aspiration hazard: Lack of data.

### Symptoms

After eye contact: Mild irritant

## 12. Ecological information

### Ecotoxicity

Further details: Bio-accumulation is not to be expected (log P(o/w) <1).

### Mobility in soil

No data available

### Persistence and degradability

Further details: Product is not biodegradable.  
Siloxanes are removed from water by sedimentation or binding to sewage sludge.

### Additional ecological information

General information: Do not allow to penetrate into soil, waterbodies or drains.

## 13. Disposal considerations

### Product

Recommendation: Incinerate according to applicable local, state and federal regulations.

### Package

Recommendation: Dispose of waste according to applicable legislation.  
Non-contaminated packages may be recycled.

## 14. Transport information

### UN number

ADR/RID, IMDG, IATA-DGR:  
not applicable

### UN proper shipping name

ADR/RID, IMDG, IATA-DGR:  
Not restricted

### Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:  
not applicable

### Packing group

ADR/RID, IMDG, IATA-DGR:  
not applicable

### Environmental hazards

Marine pollutant: no

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

### USA: Department of Transportation (DOT)

Proper shipping name: Not restricted

### Sea transport (IMDG)

Proper shipping name: Not restricted

Marine pollutant: no

### Air transport (IATA)

Proper shipping name: Not restricted

### Further information

No dangerous good in sense of these transport regulations.

## 15. Regulatory information

### National regulations - U.S. Federal Regulations

Product: All ingredients of this product are listed on the TSCA inventory.

Silicon dioxide (Quartz (SiO<sub>2</sub>)): Carcinogen Status:

IARC Rating: Group 1

OSHA Carcinogen: not listed

NTP Rating: listed

NIOSH Recommendations:

Occupational Health Guideline: 0553

### National regulations - U.S. State Regulations

Silicon dioxide (Quartz (SiO<sub>2</sub>)): California Proposition 65: cancer

### National regulations - Canada

Silicon dioxide (Quartz (SiO<sub>2</sub>)): DSL: listed

### National regulations - Great Britain

Hazchem-Code: -

## 16. Other information

Hazard rating systems:



NFPA Hazard Rating:

Health: 1 (Slight)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight)

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: B

HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0
B	

### Abbreviations and acronyms:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road  
 AS/NZS: Australian Standards/New Zealand Standards  
 CAS: Chemical Abstracts Service  
 CFR: Code of Federal Regulations  
 CLP: Classification, Labelling and Packaging  
 DMEL: Derived minimal effect level  
 DNEL: Derived no-effect level  
 EC: European Community  
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods  
 EN: European Standard  
 EQ: Excepted quantities  
 IATA: International Air Transport Association  
 IATA-DGR: International Air Transport Association – Dangerous Goods Regulations  
 IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk  
 IMDG Code: International Maritime Dangerous Goods Code  
 IMO: International Maritime Organization  
 LEL: Lower Explosion Limit  
 log P(o/w): Partition coefficient: octanol/water  
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships  
 OSHA: Occupational Safety and Health Administration  
 PBT: Persistent, bioaccumulative and toxic  
 PNEC: Predicted no-effect concentration  
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
 TRGS: Technical Rules for Hazardous Substances  
 TSCA: Toxic Substance Control Act  
 vPvB: Very persistent and very bioaccumulative

Reason of change: Changes in section 8: Occupational exposure limit values

Date of first version: 11/6/2008

### Department issuing data sheet

Contact person: see section 1: Department responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.